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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/540,024	03/31/2000	Arthur O. Tzianabos	B0801/7169	1627

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EXAMINER
LIU, SAMUEL W

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/540,024	TZIANABOS ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-146* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-146* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-36, drawn to biopolymers including non-natively polypeptide, peptide-nucleic acid and synthesized polymer, which have structural features: less than 50 KDa and containing at least two repeating positive charge motifs that are separated by spacer(s), classified in class 526, subclass 72.

II. Claims 37-62, drawn to method of inducing IL-2 secretion with non-natively synthesized **polypeptide** of structural features less than 50 KDa and containing at least two repeating charge motifs that are separated by amino acid sequence(s), classified in class 424, subclass 325 and 69.52.

III. Claims 63-64, drawn to method of treating an IL-2 responsive disorder with non-natively synthesized **polymer** (peptide-nucleic acid) of structural features: less than 50 KDa and containing at least two repeating charge motifs in which positively charged amino moieties are separated by spacer(s), classified in class 424, subclass 280.1, and class 514, subclass 7.

IV. Claims 65-102, drawn to method of protecting against abscess formation associated with bacterial infection using composition consisting of IL-2 and an activated T-cell, IL-2 and Staphylococal enterotoxin A (SEA), IL-2 and an anti-CD3 antibody, IL-2 and an oxidative chemical, and IL-2 and 94[2-formyl-3-hydroxyphenoxymethyl] benzoic acid (tucaresol), and using combination of non-natively synthesized **polymer** with anti-microbial agent(s); the polymer has structural features: less than 50 KDa and containing at least two repeating charge motifs which are separated by spacer(s); classified in class 424, subclass 85.2, 93.42, 93.71, 130.1 and 280.1, and class 514, subclass 1, 2 and 699.

V. Claims 103-107, drawn to method of activating T cell using non-natively synthesized **polymer** or **polypeptide** having structural features: less than 50 KDa

and consisting of at least two repeating charge motifs which are separated by spacer(s), classified in class 424, subclass 280.1 and class 514, subclass 2.

VI. Claims 108-110, drawn to method of treatment of disorder of inappropriate IgG response to specific antigen using non-natively synthesized **polymer** (including polypeptide) of structural features: less than 50 KDa and consisting of at least two repeating charge motifs which are separated by spacer(s), classified in class 424, subclass 280.1, and class 514, subclass 2.

VII. Claims 111-146, drawn to method of treatment of postoperative surgical adhesion using non-natively synthesized **zwitterionic non-polysaccharide** that comprises both polypeptide and polysaccharide or comprises polypeptide only, or **zwitterionic polysaccharide** that consists of polysaccharide, which all have the common features: (1) crosslinking modification; (2) consisting of at least two repeating charge motifs which are separated by spacer(s), classified in class 424, subclass 280.1, and class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Invention I is related to Invention II and V as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Invention I that are synthesized polymer or polypeptide can be used in a materially different process form Invention II process i.e. activating T cell, and Invention V process, i.e. activation of T cell, respectively, the synthesized polymer or polypeptide can be used as an antigenic molecule to produce antibodie for an immunodetection assay.

Invention I is also related to Invention III, IV, VI and VII as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Invention I, peptide-nucleic acid, can be used as hybridization probe for screening cDNA library, for example; the products of Invention IV and VI, synthesized polymer or polypeptide, can be used as an epitope to raise antibody; while the product of Invention VII, zwitterionic polypeptide-polysaccharide or polysaccharide, can be used in coating microtiter plates, for example.

Inventions II, III, IV, V, VI and VII are different methods. Invention II and V are method of stimulating an interleukin secretion and method of activating T cell, respectively; Invention III, IV and VI are different methods of treating human disorders, which are caused by an IL-2 factor, bacterial infection, irregular responsiveness of IgG to a specific antigen, respectively: whereas Invention VII is a method of treating a surgical adhesion. These methods differ from one other with respect to method steps, endpoints, targets of treatment, and ingredients; therefore, each method is patentably distinct.

Species Election

This application contains claims directed to the following patentable distinct species that are compositions of combination with use of the claimed pharmaceutical preparation of the Invention IV (Claim 75): wherein the sample is:

penicillin G,

penicillin V,

ampicillin,

amoxicillin,

bacampicillin,

cyclacillin,

epicillin,

hetacillin,

pivampicillin,

methicillin,

nafcillin,

oxacillin,

cloxacillin,

dicloxacillin,

flucloxacillin,

carbenicillin,

ticarcillin,

avlocillin,

mezlocillin,

piperacillin,

amdinocillin,

cephalexin,

cephradine,

cefadoxi,

cefaclor,

cefazolin,

cefuroxime axetil,

cefamandole,

cefonicid,

cefoxin,

cefotaxime,

ceftizoxime,

cefmenoxine,

ceftriaxone,

moxalactam,

cefotetan,

cefoperazone,

eftazidme,

imipenem,

clavulanate,

timentin,

sulbactam,

neomycin,

erythromycin,

metronidazole,

choramphenicol,

clindamycin,

lincomycin,

vancomycin,

trimethoprim-sulfamethoxazole,

aminoglycosides,

quinolones,teracyclines, or

rifampin.

Theses speicies are distinct because their structures and modes of action are different.

Applicant is required under 35 U.S.C. §121 to elect a single disclosed spies for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, or/and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

SWL

SWL
March 21, 2002

Christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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